

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION**

**MDL NO. 2326**

TO BE FILED IN LEAD CASE: Case No.: 2:12-cv-08633

THIS DOCUMENT RELATES TO:

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*Hendricks, et al. v. Boston Scientific Corporation*, 2:13-cv-03633  
*Moore v. Boston Scientific Corporation*, 2:13-cv-08802  
*Tyree, et al. v. Boston Scientific Corporation*, 2:13-cv-14397  
*Campbell v. Boston Scientific Corporation*, 2:13-cv-18786  
*Blankenship v. Boston Scientific Corporation*, 2:13-cv-22906  
*Pugh, et al. v. Boston Scientific Corporation*, 2:14-cv-01565  
*Wilson v. Boston Scientific Corporation*, 2:14-cv-05475

**DEFENDANT BOSTON SCIENTIFIC CORPORATION'S  
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS  
AND TESTIMONY OF STEPHEN H. SPIEGELBERG, PH.D.**

Defendant Boston Scientific Corporation ("Boston Scientific") submits this Memorandum in Opposition to Plaintiffs Motion to Exclude the Opinions and Testimony of Dr. Stephen H. Spiegelberg, Ph.D., and states as follows:

**INTRODUCTION**

Dr. Spiegelberg is a highly-qualified chemical engineer and polymer expert. *See* December 20, 2013 Expert Report of Dr. Spiegelberg (Attached as Exhibit A at 1). He is the president and co-founder of Cambridge Polymer Group, Inc., where he directs a team of scientist who preform contract research, analytical testing, and device development for the biomedical and polymer communities. *Id.* He has a Ph.D. in Chemical engineering from the Massachusetts Institute of Technology. *Id.* He was a post-doctoral fellow at Harvard University in the Division of Applied Sciences. *Id.* He has published numerous research articles in various fields,

including polymer chemistry, medical devices, laboratory standards and the properties of polymeric materials. *Id.* at 2.

In his December 20, 2013 MDL expert report, Dr. Spiegelberg offers opinions that are well grounded within the field of chemical engineering, polymer science and biomaterials. These include, but are not limited to, opinions regarding the safety of polypropylene, its appropriateness for use in medical devices, its safety and efficacy as a biomaterial, its biocompatibility, and that it does not degrade, contract, or shrink. As part of his opinion that polypropylene raw material was appropriate for use in Boston Scientific's devices, Dr. Spiegelberg opined that "there is no evidence that Phillips Sumika Polypropylene Company or Chevron Phillips Chemical Company had a scientific basis for the inclusion of the Medical Application Caution in the MSDS for Phillips Sumika Marlex HGX-030-01." *Id.* at 39. These opinions falls well within Dr. Spiegelberg's expertise and are directly relevant to the issues in this case. Plaintiffs do not seek to exclude any of them.

On June 2, 2014, Dr. Spiegelberg executed a supplemental report in these specific cases. June 2, 2014 Supplemental Report of Dr. Spiegelberg (Attached as Exhibit B). In his supplemental report, Dr. Spiegelberg explains that the March 7, 2014 deposition of Frank Zakrzewski "provides additional support for two of my opinions: .The Medical Application Caution in the Material Safety Data Sheet for Marlex GX-010-1 polypropylene resin has no scientific or medical basis[;] [and] The Advantage and Polyform meshes comprising Boston Scientific's pelvic mesh devices contains two different antioxidants, which further supports my opinion that the BSC mesh does not undergo oxidative degradation in vivo." *Id.* at 1. Dr. Spiegelberg also supplements the support for these pre-existing opinions by citing to and quoting from the January 2014 Position Statement on Mesh Midurethral Slings for Stress Urinary

Incontinence issued by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU).

Not surprisingly, Plaintiffs do not challenge Dr. Spiegelberg's qualifications. Plaintiffs do not challenge any of Dr. Spiegelberg's opinions set forth in his MDL expert report. Rather, Plaintiffs complain that, in his supplemental report Dr. Spiegelberg: "attempts to offer opinions about a position statement offered by medical organizations" and offers "state of mind or intent opinions related to material safety data sheets (MSDS)." Dkt. No. 216 at 2, 7. Plaintiffs' motion should be denied because Dr. Spiegelberg does not offer these opinions.

### **ARGUMENT**

Plaintiffs' Motion to Exclude the Testimony of Dr. Spiegelberg is based on a fundamental misunderstanding of the nature of Dr. Spiegelberg's supplemental expert report. Dr. Spiegelberg does not offer opinions regarding the validity of the January 2014 AUGS/SUFU position statement or the state of mind or intent of Chevron Phillips. Rather, Dr. Spiegelberg cites to, and quotes from, the AUGS/SUFU position statement and the deposition of Mr. Frank Zakrzewski to support his opinions that "[t]he Medical Application Caution in the Material Safety Data Sheet for Marlex HG-030-01 polypropylene resin has no scientific or medical basis" and that "the BSC mesh does not undergo oxidative degradation *in vivo*." Exhibit B at 1. These opinions were advanced in Dr. Spiegelberg's original report and are grounded in his expertise as a chemical engineer, a polymer scientist, and a biocompatibility expert. See Exhibit A at 20-24; 39. Plaintiffs' other arguments about Dr. Spiegelberg's supplemental report go the weight, not the admissibility, of his opinions.

**I. DR. SPIEGELBERG DOES NOT OFFER OPINIONS ABOUT THE VALIDITY OF THE JANUARY 2014 AUGS/SUFU POSITION STATEMENT.**

Plaintiffs begin their motion with an argument that the Court should exclude Dr. Spiegelberg’s “new opinions about the validity of” the January 2014 AUGS/SUFU position statement. Dkt. 216 at 2-3. Plaintiffs argue that because Dr. Spiegelberg “is not a member of AUGS or SUFU; has never treated anyone for a pelvic floor disorder, [and] has never implanted mesh in a human being” he is not qualified to offer opinions regarding the position statement. *Id.* at 3. Plaintiffs also complain (1) that Dr. Spiegelberg “opines about those organizations’ state of mind, suggesting they have determined that all polypropylene is safe for use in all surgical implants;” (2) that Dr. Spiegelberg did not know what information AUGS and SUFU relied upon when making their position statement; and (3) that he cannot establish the reliability of “hearsay statements within it.” *Id.* Plaintiffs’ arguments fail because Dr. Spiegelberg does not offer any opinions, new or otherwise, about the validity of the January 2014 AUGS/SUFU position statement, rather he cites to and quotes from this position statement as additional support for his opinions on the biocompatibility of polypropylene. See Exhibit B at 3-4.

That Dr. Spiegelberg is relying on the January 2014 AUGS/SUFU position statement, not offering opinions about it, is clear from a reading of his report. *Id.* He never offers opinions about the correctness, or validity of these statements, nor does he speculate regarding the state of mind of either organization. He simply sets forth a single quote from the statements in support of his opinions. *Id.* Dr. Spiegelberg’s reliance on this statement is plainly appropriate. Federal Rule of Evidence 703 allows an expert witness to “base an opinion on facts or data in the case that the expert has been made aware of or personally observed.” This includes inadmissible evidence—including hearsay—“[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject.” Fed. R. Evid. 703; *see also United*

*States v. Leeson*, 453 F.3d 631, 637 (4th Cir.2006) (holding that a district court did not abuse its discretion by admitting expert testimony based on hearsay when it had been “sufficiently established” that such hearsay statements were the type of information “reasonably relied upon by experts in [the] field”). Plaintiffs’ argument that Dr. Spiegelberg is offering opinions about the validity of AUGS/SUFU position statement is incorrect and the Court should reject it and deny plaintiff’s motion.

## **II. DR. SPIEGELBERG’S RELIANCE ON THE AUGS/SUFU STATEMENT IS PROPER**

Plaintiffs also seek to exclude Dr. Spiegleberg’s reliance upon and opinions derived from the AUGS and SUFU position statement by arguing that the statements itself was not generated through a scientific study and that the drafters of the statement have ties to the medical device industry. Dkt 216 at 3-7. Plaintiffs complain that “reliance on a statement of position by a private medical society should be subjected to the same rigor of scientific reliability that would apply to other material.” *Id.* at 3. Plaintiffs then argue that the position statement: (1) “is not an analysis of the literature on slings[;]” (2) “is not a Cochrane analysis[;]” (3) “is not a report of a randomized clinical trial[;]” (4) “is not peer reviewed[;]” (5) “does not reflect a scientific analysis of the published literature[;]” and (6) “neglects to take into account the differences between retropubic and obturator slings, the difference in the reports results [sic] from clinical trials on individual products, or the difference in the occurrence rates for adverse events.” *Id.* at 4-5.

Plaintiffs’ argument ignores, however, that experts may base their opinions on any facts or data that experts in the general field would reasonably rely upon when generating their opinions. There is no requirement that experts may only rely on peer reviewed studies or

scientific analysis of published literature.<sup>1</sup> The *Daubert* standard applies to Dr. Spiegelberg's opinions, not his reliance materials. See *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 856 (Fed. Cir. 2010) (“[I]t is not the district court's role under *Daubert* to evaluate the correctness of facts underlying an expert's testimony.”). Claimed “weaknesses in the factual basis of an expert witness'[s] opinion bear on the weight of the evidence rather than on its admissibility.” *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir.2000) (internal quotation marks omitted).

While Plaintiffs quibble with how the AUGS and SUFU position statement was generated, and whether it was supported by scientific data, the fact remains that AUGS and SUFU, prominent medical organizations, via their board of directors, adopted this statement. Rule 703 plainly allows Dr. Spiegelberg to rely on the fact that these leading medical organizations have adopted a statement stating that: “Polypropylene material is safe and effective as a surgical implant” and that “as a knitted implant for the surgical treatment of SUO, macorporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years” to support his opinions regarding the safety of polypropylene. Plaintiffs' criticisms of the position statement are issues for cross examination. *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006). The Court should deny Plaintiffs' motion.

### **III. DR. SPIEGELBERG DOES NOT OFFER “STATE OF MIND OR INTENT OPINIONS” RELATING TO MATERIAL SAFETY DATA SHEETS.**

Plaintiffs also argue that Dr. Spiegelberg's opinion that there is no scientific basis or safety concern underlying the medical application caution statement that was added to the polypropylene MSDS in 2004 should be excluded because “[t]hese MSDS opinions are a backdoor attempt by Dr. Spiegelberg to offer opinions about Chevron Philips state of mind or

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<sup>1</sup> Indeed, if such a requirement existed, it would require excluding the vast majority of the materials that plaintiffs' experts relied upon when generating their opinions.

intent ....” Dkt. 206 at 7. Dr. Spiegelberg is doing nothing of the sort. Rather, he is offering a biocompatibility/biomaterials opinion regarding whether there is a scientific or safety justification supporting the MSDS’s medical application caution statement.

In support of their argument, Plaintiffs mistakenly suggest that Dr. Spiegelberg’s opinion about the lack of any scientific or safety basis for the MSDS’s medical application caution statement is based solely on his reading of Mr. Zakrzewski’s deposition. Rather, as explained in Dr. Spiegelberg’s supplemental report, his opinion is based on (1) Mr. Zakrzewski’s testimony, (2) testing performed by Boston Scientific to determine the “suitability of use” of the Advantage and Polyform meshes for permanent medical applications; (3) biocompatibility testing which demonstrate that the material is safe for permanent use in the human body (4) leaching studies demonstrating that there are no biological responses to any potential leachable materials; (5) the fact that polypropylene has “a long history of safe and effective use in various medical applications, including use as a surgical mesh”; and (6) the statements about polypropylene contained in the January 2014 AUGS/SUFU position statement. Exhibit B at 1-4.

Plaintiffs assert in a footnote that Dr. Spiegelberg is unqualified to offer opinions related to MSDS’s because he has “offered no evidence in his reports, deposition, or resume that he has any experience in creating, reviewing, or analyzing MSDS.” Dkt. 216 at 7 n. 2. While an expert may not testify outside his or her field of expertise, the mere fact that a statement is contained in an MSDS does not mean that only an MSDS expert may offer opinions interpreting it. Here the statement at issue discusses whether it is appropriate to implant polypropylene in the human body and/or expose it to bodily tissues and fluids. This statement relates to biomaterials generally and the biocompatibility of polypropylene specifically. Dr. Spiegelberg, a chemical

engineer, polymer scientist, and biomaterials expert, is more than qualified to comment on whether the statement is supported by safety concerns or scientific data.

Dr. Spiegelberg's opinions regarding the medical application caution statement in the polypropylene MSDS were derived through a reliable methodology that was fully delineated in his initial expert report. Dr. Spiegelberg is not offering a speculative, subjective opinion regarding the state of mind of Chevron Phillips or the person who drafted that particular statement; he is offering a fact-based, objective opinion based on the state of biomaterial science and the information known about polypropylene. The Court should deny Plaintiff's Motion.

#### **IV. PLAINTIFFS' DISAGREEMENTS WITH DR. SPIEGELBERG'S INTERPRETATION OF MR. ZAKREWSKI'S TESTIMONY DO NOT WARRANT EXCLUSION.**

Plaintiffs' primary argument regarding Dr. Spiegelberg's discussion of and citation to Mr. Zakrzewski's testimony centers upon their disagreement with Dr. Spiegelberg's interpretation of the testimony. Plaintiffs argue that "when one looks at Ms. Zakrzewski's actual deposition, it does not say what Dr. Spiegelberg claims it says." Dkt. No. 216 at 8. Plaintiffs incorrectly complain that "Dr. Spiegelberg's supplemental report restating[sic] his version of testimony rather than quoting from the transcript citations." *Id.* at 8.<sup>2</sup> Plaintiffs then argue that claimed "inaccuracies" in Dr. Spiegelberg's reading of the deposition and alleged "misquoted" and "re-craft[ed]" testimony constitute methodological flaws that warrant exclusion. *Id.* at 10.

Dr. Spiegelberg's reading of Mr. Zakrzewski's testimony is reasonable and accurate. He quotes directly and accurately from portions of the deposition transcript. Exhibit B at 1-3. The quoted testimony and the passages cited by Dr. Spiegelberg speak for themselves and support Dr. Spiegelberg's interpretation. Indeed, the only Court that has addressed this testimony, The

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<sup>2</sup> Dr. Spiegelberg's Supplemental Report contains numerous direct quotations from Mr. Zakrzewski's deposition. See Exhibit B at 2-3.



Middlesex County Superior Court (Massachusetts), came to the same conclusion as Dr. Spiegelberg and rejected Plaintiffs' contention that the MSDS medical application caution statement was supported by safety concerns or any scientific basis as speculative:

The record establishes that Chevron Phillips made no determination as to the suitability of Marlex for particular applications. *See, e.g.*, 3/17/14 Zakrzewski Dep. at 45-47, 63-66, 75, 107, 134-135, 137-138. Further, the plaintiff's contention that the inclusion of the Medical Application Caution in the MSDS was predicated on concerns regarding the effect of oxidation or on any scientific data or tests, as opposed to an effort to avoid liability for use of the material in medical applications, is speculative.<sup>3</sup>

In any event, even if Plaintiffs were correct, their disagreement with Dr. Spiegelberg's interpretation of Ms. Zakrzewski's testimony would not warrant exclusion. Plaintiffs' disagreement with Dr. Spiegelberg's interpretation Ms. Zakrzewski's testimony does not warrant exclusion. "[I]t is not the district court's role under *Daubert* to evaluate the correctness of facts underlying an expert's testimony." *i4i Ltd. P'ship*, 598 F.3d at 856. There is no requirement that "proffered expert testimony [be] irrefutable or certainly correct." *Moreland*, 437 F.3d at 431 (internal quotations omitted). Rather, [a]s with all other admissible evidence, expert testimony is subject to testing by [v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Id.* Plaintiffs' disagreement with Dr. Spiegelberg's interpretation of Mr. Zakrzewski's testimony goes to the weight, not the admissibility, of his opinions. Plaintiffs can challenge Dr. Spiegelberg's interpretation of Mr. Zakrzewski's testimony during cross examination. The Court should deny Plaintiffs' motion.

### CONCLUSION

For all of the foregoing reasons, the Court should deny Plaintiffs' motion to exclude the opinions and testimony of Dr. Spiegelberg.

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<sup>3</sup> Order on Certain Motions in Limine, *Albright v. Boston Scientific Corp.*, No. 2012-0909 (Super. Ct. Civ. Mass., June 27, 2014), a true and accurate copy of which is attached hereto as Exhibit C.

Dated: August 11, 2014

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 11, 2014, a true and correct copy of the forgoing was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: August 11, 2014

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